MAY 2 3 2000

K000957

510(k) Summary of Safety and Effectiveness for the Hoffmann® II Hybrid Frame System

Proprietary Name:	Hoffmann® II Hybrid Frame System
Common Name:	External Fixation Frame Components
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Regulatory Class:	Class II
Device Product Code:	87 LXT
For Information contact:	Karen Ariemma, Regulatory Affairs, Allendale Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 760-8187 Fax: (201) 760-8234

Intended Use:

This submission describes external fixation frame components when used together with the components of the Hoffmann® II External Fixation System and Monotube Triax™ External Fixation System and used in conjunction with Half Pins and Wires provide hybrid frame constructs. This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

Description:

The Hoffmann® II Hybrid Frame system consists of five components described below

1) Carbon Ring, 2) Ring Clamp, 3) Wire Post, 4) Pin Post and 5) Ring to Monotube® TRIAX™ Tube Clamp.

- The Carbon Ring has a polygonal cross section. It is an open ring design allowing for placement on the limb. The carbon ring is radiolucent and lightweight. The ring is fabricated from a carbon fiber/epoxy composite material.

- The Ring Clamp is designed to provide a versatile connection between the ring and a wire or an Apex™ pin. The clamp allows accurate placement around the ring to facilitate fracture management and strategic wire or pin placement. The clamp is manufactured from Stainless Steel.

- The Wire Post is designed to allow three-dimensional placement of the wire to facilitate fracture management. The clamp is manufactured from Stainless Steel.

- The Pin Post is designed to allow three-dimensional placement of the Apex™ Pin to facilitate fracture management. The clamp is manufactured from Stainless Steel.

- The Ring to Monotube® TRIAX™ Tube Clamp is designed to connect the Carbon Ring to a Monotube® TRIAX™ dynamic or carbon tube. The clamp provides for angulation between the circular frame and the tube of the external fixation frame system. The clamp is manufactured from Stainless Steel and Aluminum.

Substantial Equivalence:

Equivalency of this device is based on similarities in intended use, materials, design and operational principles to the Howmedica Monotube® TRIAX™ System, Synthes AO/ASIF Hybrid Fixator and the Ace-Fischer® Hybrid Fixator.

Testing of the subject components demonstrates substantial equivalence to other predicate hybrid frame components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Ms. Elizabeth A. Staub
Vice President, Quality Assurance/Regulatory Compliance/Clinical Research
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401

Re: K000957
Trade Name: Hoffman II External Fixation System
Regulatory Class: II
Product Code: LXT
Dated: March 23, 2000
Received: March 24, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vachner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000957

Device Name: Hoffmann® II Hybrid Frame System

Indications For Use:

The Hoffmann® II Hybrid External Fixation System is intended to be used in conjunction with the Apex™ Half Pins of the Hoffmann® External Fixation System and Kirschner Wires of the Monticelli Spinelli™ External Fixation System, and may be used as a Hybrid External Fixation System with the components of the Hoffmann® II External Fixation System and the Monotube® TRIAX™ External Fixation System.

This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K000957

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)